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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,229	06/26/2003	Manfred Bohn	3804.1596-01	4228
22852	7590	06/29/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

### Application No.

10/606,229

### Applicant(s)

BOHN ET AL.

### Examiner

Vickie Kim

### Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/077194.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

***New Matter***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The claim 24 recites "one phase" at page 10, line 18. However, there is no support found in the instant specification for the phrase whereas the instant specification teaches a various pharmaceutical preparations in the form of hair lotions, shampoos, liquid soaps, as well as cream and gel preparations at page 5, lines 24-28. However, the said formulations are not enough to support the claimed language. There is no sufficient evidence to convey to one of ordinary skill in the art that applicant was in possession of the claimed invention. Therefore, the claims fail to comply with the written description requirement.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 16-29 are rejected under 35 U.S.C. 103(a) as being obvious over Lange(US 5,132,107) alone, or alternatively in view of Durrant et al(US 4,699,924) or Saint-Leger(US 5,650,145).

The claims are drawn to a method of treating seborrheic dermatitis using the composition consisting essentially of at least one 1-hydroxy-2-pyridone of general formula I as recited in the claim 14.

Lange(US'107, hereafter) teaches a composition having two phases wherein the second phase comprises a physiologically acceptable acid component and an effective antimycotic compound(i.e. piroctone olamine) which has antiseborrheic effect, see abstract and column 5, lines 15-65. US'107 further teaches that the second phase of the composition has a pH about from 3 to 6, preferably from 4 to 5. US'107 further teaches optional additives such as an organic acid(e.g. salicylic, lactic acid) and adjuvants such as rinsing agent for extra benefits.

Although applicant's claims differ from US'107 because they require seborrheic dermatitis.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to utilize the composition of US'107 to treat not only dandruff but also seborrheic dermatitis because US'107 clearly suggests that phase II composition has specific therapeutic effects resulted from active component such as piroctone olamine (antiseborrheic agent) ,see col. 5, lines 15-65. Thus, it would have been readily apparent to any ordinary skilled artisan that the composition according to the patent(US'107) would have treated the

seborrheic dermatitis as well as dandruff when piroctone olamine is selected and used as the active agent to formulate the therapeutic modality.

One would have been motivated to do so because it is always desired to extend the industrial applicability using the drug that has been known in the art because the safety and the effective dosage regimen are known or easily optimized to obtain maximum benefits including low manufacturing cost and better consumer acceptability with assurance. It is noted that the claims are drawn to a composition comprising an active component. Thus, the claimed subject matter of the instant claims are embraced by the scope of the composition(US'107) having two phases wherein the piroctone olamine is effectively used as an active component, see column 4, lines 45-52.

As to the claims 15-18, wherein the claims require specific species such as piroctone olamide having octyl radical which is suggested by the cited reference(i.e. piroctone olamine as an active agent ). Although US'017 does not explicitly use the term"surfactant", US'107 teaches "quats(quaternary ammonium compounds" which are, in fact, surfactant. Quats are used to enhance rinsing effects as suggested at column 6, lines 53-55. And thus, the functionality of surfactant are inherently met by the cited reference and the claims are properly included in this rejection.

As to the claims 19-23, US'107 teaches shampoo formulation, see abstract. Thus, all the claims are properly included in this rejection.

All the critical elements required by the instance claims are obvious over the teaching of the cited reference and the claimed subject matter is not considered to be patentably distinct over the prior art of the record.

Applicant's claim 24 is different from US'107 because it requires one phase composition.

Durrant teaches an one phase antidandruff cream consisting essentially of OCTOPIROX as an active agent and surfactant(i.e. EMULSENE 1219). For instance, the pH of Durrant's patented composition is adjusted to pH 4.5 with triethanolamine, see column 14, lines 50.

Thus, one would have been motivated to make one phase composition containing 1-hydroxy 2-pyrones as an active agent to treat seborrheic dermatitis when these references are taken together because the deficiency of US'107(i.e. making one phase composition using same ingredients, having same utility) are remedied by Durrant(US'924). Since antiseborrheic effect of antidandruff shampoo composition utilizing 1-hydroxy-2-pyridone is already taught by the Lange(US'107), one would have been motivated to use Durrant's one phase antidandruff shampoo containing 1-hydroxy-2-pyridines to treat seborrheic dermatitis and expected reasonable success from the said treatment.

One would have been motivated to do so to make the cost-effective product when it combines in one product and improve the compliance that leads to higher therapeutic effects. It is noted that antiseborrheic effects is naturally achieved when one phase shampoo is applied. Thus, to prevent or treat dandruff effectively, one would have been apply the one phase shampoo to treat

seborrheic dermatitis because it is also conventionally known that dandruff is often considered as a manifestation seen in the patient having seborrheic dermatitis.

Applicant's claims 15, 20 and 27 differ because they require 1-hydroxy-2-pyridone with cyclohexyl radical substitution in R4 position. Applicant's claim 26 requires foam. Saint-Leger teaches the treatment of seborrheic dermatitis using Octopirox or Ciclopirox as effective active agent in the form of foam, lotion or shampoo(see column 2, lines 29-32 and examples). Thus, it would have been obvious to one of ordinary skill in the art to substitute one to another as suggested by Saint-Leger. One would have motivated to so for better selection or accessibility, and to fit in one's preference.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 16-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/077194(not available—board of appeal).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are drawn to same treatment of seborrheic dermatitis using 1-hydroxy 2-pyridone compounds having the same generic formula. Thus, the scope of the claimed subject matter is embraced by one to the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579(fax: 571-273-0579). The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-746-3165 for



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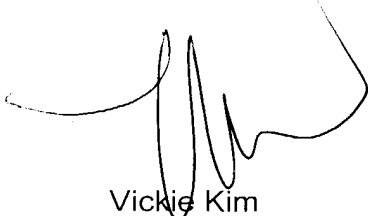
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After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist

whose ~~VICKIE KIM~~ number is 571-272-1600.

**PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Vickie Kim', with a stylized, flowing script.

Vickie Kim  
June 14, 2004  
Art unit 1614